

EXHIBIT A

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8 Attorneys for Plaintiffs

9 SUPERIOR COURT OF CALIFORNIA

10 COUNTY OF SAN FRANCISCO

11 MELONEY WRIGHT and DONNY
12 WRIGHT, wife and husband; DANYELE
13 BACON, a single woman; DIANA BURK, a
14 single woman; TINA LEIPHART, a single
15 woman; NUBIA FLORES, a single woman;
16 MOLLY KIRKPATRICK, a single woman;
17 REYNALDA ALVARADO, a single
18 woman; GAYLE ANDERSON, a single
19 woman; VERONIQUE PETERS and
20 DONNY PETERS, wife and husband;
21 LAKEYA BASKOM, a single woman;
22 TIFFANY LILLIE, a single woman, and
23 LORRAINE FONTANILLA-WEBBER, on
24 behalf of her minor daughter, ASHLEY
25 WEBBER,

26 Plaintiffs,

vs.

18 ORTHO-MCNEIL CORPORATION, a
19 foreign corporation; JOHNSON &
20 JOHNSON, a foreign corporation;
21 JOHNSON & JOHNSON SERVICES,
22 INC., a foreign corporation; JOHNSON &
23 JOHNSON HEALTH CARE SYSTEMS,
24 INC., a foreign corporation; JOHNSON &
25 JOHNSON RESEARCH &
26 DEVELOPMENT, LLC., a foreign
corporation; JOHNSON & JOHNSON
CONSUMER COMPANIES, INC., a
foreign corporation; MCKESSON
CORPORATION, a Delaware corporation;
ALZA CORPORATION, a California
corporation aka ALZA DEVELOPMENT
aka ALZA INTERNATIONAL, INC., and
DOES 1-50,

ENDORSED
FILED
San Francisco County Superior Court

FEB 14 2007

BY: GORDON PARK-LI, Clerk
CRISTINA E. BAUTISTA
Deputy Clerk

JUL 20 2007 - 9 AM

DEPARTMENT 212

No. CCC07-460481

COMPLAINT FOR DAMAGES

and

CCC07-460481
DEMAND FOR JURY TRIAL

1
2 Defendants.

3 For their Complaint against the defendants, Plaintiffs allege:

4 **PARTIES**

5 1. Plaintiff MELONEY WRIGHT and DONNY WRIGHT are wife and husband
6 and citizens of the State of California. Meloney Wright was prescribed and used Ortho
7 Evra™.

8 2. Plaintiff DANYELE BACON is a citizen of the State of California, and was
9 prescribed and used Ortho Evra™.

10 3. Plaintiff DIANA BURK is a citizen of the State of Arizona, and was prescribed
11 and used Ortho Evra™.

12 4. Plaintiff TINA LEIPHART is a citizen of the State of Arizona, and was
13 prescribed and used Ortho Evra™.

14 5. Plaintiff NUBIA FLORES is a citizen of the State of Arizona, and was
15 prescribed and used Ortho Evra™.

16 6. Plaintiff MOLLY KIRKPATRICK is a citizen of the State of Arizona, and was
17 prescribed and used Ortho Evra™.

18 7. Plaintiff REYNALDA ALVARADO is a citizen of the State of Arizona, and
19 was prescribed and used Ortho Evra™.

20 8. Plaintiff GAYLE ANDERSON is a citizen of the State of Iowa, and was
21 prescribed and used Ortho Evra™.

22 9. Plaintiff LAKEYA BASKOM is a citizen of the State of Arizona, and was
23 prescribed and used Ortho Evra™.

24 10. Plaintiff TIFFANY LILLIE is a citizen of the State of Arizona, and was
25 prescribed and used Ortho Evra™.

26 11. Plaintiffs VERONIQUE PETERS and DONNY PETERS are wife and husband

1 and citizens of the State of Arizona, and Plaintiff Veronique Peters was prescribed and used
2 Ortho Evra™.

3 12. Plaintiff LORRAINE FONTANILLA-WEBBER is a citizen of the State of
4 Arizona, and brings this action on behalf of her minor daughter, ASHLEY WEBBER, who
5 was prescribed and used Ortho Evra™.

6 13. Johnson & Johnson (hereafter, "Johnson & Johnson"), is a corporation
7 organized and existing under the laws of the State of New Jersey, with its principal place of
8 business in New Jersey. Johnson & Johnson was and is authorized to do business in the State
9 of California and was engaged in substantial commerce and business activity in the County
10 of San Francisco.

11 14. Johnson & Johnson, a foreign corporation; Johnson & Johnson Services, Inc.,
12 Johnson & Johnson Health Care Systems, Inc., Johnson & Johnson Research &
13 Development, LLC., and Johnson & Johnson Consumer Companies, Inc., are divisions of
14 Johnson & Johnson, are either organized under the laws of California, New Jersey or
15 Delaware, and are named herein as other companies very closely related to Johnson &
16 Johnson, and who may also have been involved in the design, promotion, sale, and/or
17 distribution of Ortho Evra™, and will be referred to collectively as "Johnson & Johnson",
18 until such time as their involvement becomes more evident.

19 15. Defendant McKesson Corporation (hereafter, "McKesson") was and is a
20 corporation organized and existing under the laws of the State of Delaware, with its principal
21 place of business in San Francisco, California. McKesson was and is authorized to do
22 business in the State of California and was engaged in substantial commerce and business
23 activity in the County of San Francisco.

24 16. Defendant Alza Corporation (hereafter, "Alza") was and is a corporation
25 organized and existing under the laws of the State of Delaware, with its principal place of
26 business in San Jose, California, was and is authorized to do business in the State of

1 California, is a subsidiary corporation of Defendant Johnson & Johnson and was engaged in
2 substantial commerce and business activity in the County of San Francisco.

3 17. Ortho-McNeil (hereafter, "Ortho-McNeil") is a corporation organized and
4 existing under the laws of the State of New Jersey, with its principal place of business in
5 New Jersey, was and is authorized to do business in the State of California, is a subsidiary
6 corporation of Defendant Johnson & Johnson, and was engaged in substantial commerce and
7 business activity in the County of San Francisco.

8 18. The true names or capacities, whether individual, corporate, or otherwise, of
9 Defendants Does 1-50, are unknown to Plaintiffs who therefore sue said Defendants by such
10 fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein
11 by fictitious names is in some manner legally responsible for the events and happenings
12 herein referred to and proximately caused foreseeable damages to Plaintiffs as alleged herein.

13 19. At all times herein mentioned, "Defendants" include all named Defendants
14 herein as well as Defendants Does 1-50.

15 20. At all relevant times Defendants, through their agents, servants, employees and
16 apparent agents, were the designers, manufacturers, marketers, distributors and/or sellers of
17 Otho Evra™, which is the only birth control drug which is delivered by a transdermal patch.

18 21. Defendants, either directly or through their agents, apparent agents, servants
19 or employees, at all relevant times, sold and distributed Ortho Evra™ in the States of
20 California, Arizona, Mississippi, Iowa, and in other states and foreign countries.

21 22. Defendants derive substantial revenue from pharmaceutical products used or
22 consumed in the State of California.

23 23. Defendants expected or should have expected, that their business activities
24 could or would have consequences within the State of California, as well as throughout the
25 United States.

26 24. Plaintiffs bring this action to recover damages, restitution, refunds, loss of

1 consortium and/or for equitable, injunctive and declaratory relief against Defendants.

2 25. Defendants placed Ortho Evra™ into the stream of worldwide commerce and
3 interstate commerce in the United States. It did so without adequate testing and with no
4 warning that the drug carried with it a risk of causing thromboembolytic and myocardial
5 events, far in excess of those risks associated with other forms of birth control.

6 26. Plaintiffs need continued medical monitoring to prevent or mitigate the future
7 onset of thromboembolytic and myocardial events which have already manifested.

8 27. Defendants did directly and/or through authorized agents, sell and/or distribute
9 Ortho Evra™ to each individual Plaintiff.

10 SUMMARY OF THE CASE

11 28. Defendants, either directly or through their agents, apparent agents, servants
12 or employees, designed, manufactured, marketed, advertised, distributed and sold Ortho
13 Evra™ as the only transdermal delivery birth control device.

14 29. As a result of the defective nature of Ortho Evra™, persons who were
15 prescribed and used Ortho Evra™, including Plaintiffs, have suffered and may continue to
16 suffer severe and permanent personal injuries, including, but not limited to,
17 thromboembolytic and myocardial events.

18 30. Defendants concealed and continue to conceal their knowledge of Ortho
19 Evra™'s unreasonably dangerous risks from Plaintiffs, other consumers, and the medical
20 community.

21 31. Defendants failed to conduct adequate and sufficient post marketing
22 surveillance of Ortho Evra™ after it began marketing, advertising, distributing, and selling
23 the drug.

24 32. As a result of Defendants' actions and inaction, Plaintiffs were injured due to
25 use of Ortho Evra™, which has caused and will continue to cause Plaintiffs various injuries
26 and damages. Plaintiffs accordingly seek compensatory damages.

FACTUAL BACKGROUND

33. At all relevant times Defendants were responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling Ortho Evra™.

34. In 2002, the United States Food and Drug Administration ("FDA") approved Ortho Evra™ as a transdermal delivery system of hormone replacement birth control, but that Defendants intentionally/recklessly and/or negligently, did not give the FDA complete and adequate information upon which the FDA could have made a complete and adequate evaluation of this drug, and had the FDA been given such information, the label and/or warnings, would have been different and/or the approval would not have occurred.

35. At all times pertinent, agents of Defendants did act in concert to sell and promote Ortho Evra™.

36. Before, during and after Ortho Evra™ was introduced, promoted and sold, key agents of Defendants who knew or should have known of the dangerous propensities of Ortho Evra™, went to work for other named Defendants, and continued to introduce, promote, sell and distribute Ortho Evra™.

37. Despite test results indicating an increased risk of thrombolytic events, the warnings associated with Ortho Evra™ ignored those facts.

38. Throughout the early years of its distribution, medical articles and studies appeared reporting the frequent and common occurrence of clotting and heart problems associated with women who were on Ortho Evra™, at rates far higher than associated with other oral contraceptives.

39. Defendants knew and or should have known that such reports indicated Ortho Evra™ was the cause of these problems and that the risks associated with use were far outweighed by the convenience of the use of a transdermal delivery system with the formulation of Ortho Evra™.

40. Defendants claim that Ortho Evra™ helps prevent pregnancy the same way

1 birth control pills do by preventing ovulation, by thickening the cervical mucus, and by
2 changing the endometrium to reduce the chance of implantation.

3 41. Unlike birth control pills, the Ortho Evra™ birth control patch is transdermal,
4 meaning continuous levels of the hormones norelgestromin and ethinyl estradiol (progestin
5 and estrogen, respectively) are delivered through the skin into the bloodstream, so that the
6 amount of hormone delivered is far higher than ordinary oral contraceptives.

7 42. On November 10, 2005, in the face of extreme pressure from the FDA,
8 Defendants updated the prescribing information for Ortho Evra™ to include a new warning
9 and provide additional information on the differences between Ortho Evra™ in a weekly
10 transdermal delivery system and a daily oral delivery system. The new warning states:

11 The pharmacokinetic (PK) profile for the Ortho Evra™ patch
12 is different from the PK profile for oral contraceptives in that it
13 has higher steady state concentrations and lower peak
14 concentrations. AUC and average concentration at steady state
15 for ethinyl estradiol (EE) are approximately 60% higher in
16 women using Ortho Evra™ compared with women using an oral
17 contraceptive containing EE 35 mg. In contrast, peak
18 concentrations for EE are approximately 25% lower in women
19 using Ortho Evra™. Inter-subject variability results in increased
20 exposure to EE in some women using either Ortho Evra™ or
21 oral contraceptives. However, inter-subject variability in women
22 using Ortho Evra™ is higher. In general, increased estrogen
23 exposure may increase the risk of adverse events. However, it is
24 not known whether there are changes in the risk of serious
25 adverse events based on the differences in pharmacokinetic
26 profiles of EE in women using Ortho Evra™ compared with
women using oral contraceptives containing 35mg of EE.

20 43. The new label dated November 10, 2005, also contains a new section entitled
21 "Transdermal versus Oral Contraceptives." In a study of 32 healthy female volunteers, it was
22 found that the overall exposure for NGMN [norelgestromin] and EE [ethinyl estradiol] (AUC
23 and C_{ss}) was higher in subjects treated with Ortho Evra™ for both Cycle 1 and Cycle 2,
24 compared to that for the oral contraceptive, while C_{max} values were higher in subjects
25 administered the oral contraceptive. Under steady-state conditions, AUC₀₋₁₆₈ and C_{ss},
26 EE were approximately 55% and 60% higher, respectively, for the transdermal patch, and the

1 Cmax was about 35% higher for the oral contraceptive, respectively. Inter-subject variability
2 (%CV) for the PK parameters following delivery from Ortho Evra™ was higher relative to
3 the variability determined from the oral contraceptive.

4 44. The November 10, 2005 label also provides that in the study of 32 healthy
5 female volunteers, the percent change in systemic estrogenic activity related to the Sex
6 Hormone Binding Globulin (SHBG) was higher for Ortho Evra™ users compared to women
7 taking the oral contraceptive.

8 45. In the face of the problems associated with the formulation of Ortho Evra™,
9 Defendants changed the formulation and warnings in the Canadian equivalent of Ortho
10 Evra™, but did not do the same in the United States.

11 46. Defendants did knowingly and/or negligently and/or recklessly and/or
12 maliciously employ qualified and unqualified researchers who falsely and/or negligently
13 and/or maliciously, ignored the dangers associated with Ortho Evra™ at a time when
14 Defendants could have avoided injuries sustained by these Plaintiffs.

15 47. Defendants did employ qualified and unqualified researchers who
16 systematically ignored the dangers associated with Ortho Evra™ and falsely and/or
17 negligently and/or recklessly and/or maliciously reported to Defendants, the FDA, health care
18 providers and the public that the risks associated with Ortho Evra™ were the same as any
19 other form of hormonal replacement birth control drug.

20 48. Defendants knew of the significant risk of dental and oral complications caused
21 by use of Ortho Evra™, but Defendants did not adequately and sufficiently warn consumers,
22 including Plaintiffs, or the medical community, of such risk.

23 49. As a direct result, Plaintiffs were prescribed Ortho Evra™ and have been
24 permanently and severely injured, having suffered serious consequences from the use of
25 Ortho Evra™. Plaintiffs require and will in the future require ongoing medical care and
26 treatment.

1 50. Plaintiffs has suffered mental anguish from the knowledge that Plaintiffs will
2 have life-long complications as a result of the injuries Plaintiffs sustained from the use of
3 Ortho Evra™.

4 51. Plaintiffs were prescribed and used Ortho Evra™ in a foreseeable manner
5 pursuant to their respective prescriptions.

6 52. Plaintiffs, as a direct and proximate result of using Ortho Evra™, suffered
7 severe mental and physical pain and suffering and has sustained permanent injuries and
8 emotional distress.

9 53. Plaintiffs used Ortho Evra™ which had been provided in a condition that was
10 substantially the same as the condition in which it was manufactured and sold.

11 54. Plaintiffs would not have used Ortho Evra™ had Defendants properly
12 disclosed the risks associated with the drug. Alternatively, Plaintiffs would have known
13 and/or recognized the precursors to thrombolytic and myocardial events, they may have been
14 able to avoid the clinical manifestation of these problems.

15 55. Defendants, through their affirmative misrepresentations and omissions,
16 actively concealed from Plaintiffs and their physicians the true and significant risks
17 associated with taking Ortho Evra™. The running of any applicable Statute of Limitations
18 has been tolled by reason of Defendants' fraudulent concealment.

19 56. As a result of Defendants' actions, Plaintiffs and prescribing physicians were
20 unaware, and could not have reasonably known or have learned through reasonable diligence,
21 that Plaintiffs had been exposed to the risk identified in this complaint, and that those risks
22 were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

23 57. Defendants actions amounted to overpromotion.

24 58. Defendants actions do not meet the criteria necessary to overcome the
25 "Reasonable Expectations Doctrine".

26

FIRST CAUSE OF ACTION
(Negligence)

59. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

60. Defendants owed Plaintiffs, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and/or selling Ortho Evra™.

61. Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test Ortho Evra™ before releasing the drug to market;

b. Failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Ortho Evra™;

c. Failing to conduct sufficient post-market testing and surveillance of Ortho Evra™;

d. Designing, manufacturing, marketing, advertising, distributing, and selling Ortho Evra™ to consumers, including Plaintiffs, without an adequate warning of the significant and dangerous risks of Ortho Evra™ and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. Failing to exercise due care when advertising and promoting Ortho Evra™; and,

f. Negligently continuing to manufacture, market, advertise, and distribute Ortho Evra™ after Defendants knew or should have known of its adverse effects.

62. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered serious personal injuries. In addition, Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will

1 continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life,
2 increased risk of premature death, aggravation of preexisting conditions and activation of
3 latent conditions, and other losses and damages. Plaintiffs have incurred and will continue
4 to incur direct medical losses and costs include care for hospitalization, physician care,
5 monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue
6 to incur mental and physical pain and suffering. Plaintiffs have suffered loss of wages and
7 wage-earning capacity.

8 63. Defendants' conduct as described above was committed with knowing,
9 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
10 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages
11 so as to punish Defendants and deter them from similar conduct in the future.

12 WHEREFORE, Plaintiffs demand judgment against Defendants and seek
13 compensatory damages, and exemplary and punitive damages together with interest, the costs
14 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

15 **SECOND CAUSE OF ACTION**
16 **(Products Liability)**

17 64. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

18 65. Defendants manufactured, sold, distributed, marketed, and/or supplied Ortho
19 Evra™ in a defective and unreasonably dangerous condition to consumer, including
20 Plaintiffs.

21 66. Defendants designed, manufactured, sold, distributed, supplied, marketed,
22 and/or promoted Ortho Evra™, which was expected to reach and did in fact reach
23 consumers, including Plaintiffs, without substantial change in the condition in which it was
24 manufactured and sold by Defendants.

25 67. Plaintiffs used Ortho Evra™ as prescribed and in a manner normally intended,
26 recommended, promoted and marketed by Defendants.

1 68. Ortho Evra™ failed to perform safely when used by ordinary consumers,
2 including Plaintiffs, including when it was used as intended and in a reasonably foreseeable
3 manner.

4 69. Ortho Evra™ was defective in its design and was unreasonably dangerous in
5 that its risks exceeded the benefits associated with its design or formulation.

6 70. Ortho Evra™ was defective in design or formulation in that it posed a greater
7 likelihood of injury than other similar medications and was more dangerous than an ordinary
8 consumer could reasonably foresee or anticipate.

9 71. Ortho Evra™ was defective in its design and was unreasonably dangerous in
10 that it neither bore nor was packaged with nor accompanied by warnings adequate to alert
11 consumers, including Plaintiffs, of the risks described herein, including, but not limited to,
12 the risk of thromboembolic and/or thrombolytic events.

13 72. Although Defendants knew or should have known of the defective nature of
14 Ortho Evra™, it continued to design, manufacture, market, and sell Ortho Evra™ so as to
15 maximize sales and profits at the expense of the public health and safety. By so acting,
16 Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by
17 Ortho Evra™.

18 73. Plaintiffs could not, through the exercise of reasonable care, have discovered
19 Ortho Evra™'s defects or perceived the dangers posed by the drug.

20 74. As a direct and proximate consequence of Defendants' conduct, Plaintiffs
21 suffered serious personal injuries. In addition, Plaintiffs required and will continue to require
22 healthcare. Plaintiffs have incurred and will continue to incur medical and related expenses,
23 Plaintiffs also have suffered and will continue to suffer diminished capacity for the
24 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation
25 of preexisting conditions and activation of latent conditions, and other losses and damages
26 Plaintiffs' direct medical losses and costs include care for hospitalization, physician care,

1 monitoring, treatment, medications, and supplies. Plaintiffs incurred and will continue to
2 incur mental and physical pain and suffering. Plaintiffs suffered loss of wages and
3 wage-earning capacity.

4 75. Defendants' conduct as described above was committed with knowing,
5 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
6 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages
7 so as to punish Defendants and deter them from similar conduct in the future.

8 WHEREFORE, Plaintiffs demand judgment against Defendants and seek
9 compensatory damages, and exemplary and punitive damages together with interest, the costs
10 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

11 **THIRD CAUSE OF ACTION**
12 **(Breach of Express Warranty)**

13 76. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

14 77. Defendants expressly represented to Plaintiffs and other consumers and the
15 medical community that Ortho Evra™ was safe and fit for its intended purposes, that it was
16 of merchantable quality, that it did not produce any dangerous side effects, and that it was
17 adequately tested.

18 78. Ortho Evra™ does not conform to Defendants' express representations because
19 it is not safe, has numerous and serious side effects, and causes severe and permanent
20 injuries.

21 79. At all relevant times Ortho Evra™ did not perform as safely as an ordinary
22 consumer would expect, when used as intended or in a reasonably foreseeable manner.

23 80. Plaintiffs, other consumers, and the medical community relied upon
24 Defendants' express warranties.

25 81. As a direct and proximate result of Defendants' actions, Plaintiffs suffered
26 serious personal injuries. In addition, Plaintiffs required and will continue to require

1 healthcare and services. Plaintiffs incurred and will continue to incur medical and related
 2 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the
 3 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation
 4 of preexisting conditions and activation of latent conditions, and other losses and damages.
 5 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include
 6 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
 7 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.
 8 Plaintiffs have suffered loss of wages and wage-earning capacity.

9 82. Defendants' conduct as described above was committed with knowing,
 10 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
 11 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages
 12 so as to punish Defendants and deter them from similar conduct in the future.

13 **WHEREFORE**, Plaintiffs demand judgment against Defendants and seeks
 14 compensatory damages, and exemplary and punitive damages together with interest, the costs
 15 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

16 **FOURTH CAUSE OF ACTION**
 17 **(Breach of Implied Warranty)**

18 83. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

19 84. Defendants manufactured, distributed, advertised, promoted and sold Ortho
 20 Evra™.

21 85. At all relevant times, Defendants knew of the use for which Ortho Evra™ was
 22 intended and impliedly warranted the product to be of merchantable quality and safe and fit
 23 for such use.

24 86. Defendants were aware that consumers, including Plaintiffs, would use Ortho
 25 Evra™ for treatment of osteoporosis and for other purposes.

26 87. Plaintiffs and the medical community reasonably relied upon the judgment and

1 sensibility of Defendants to sell Ortho Evra™ only if it was indeed of merchantable quality
2 and safe and fit for its intended use.

3 88. Defendants breached their implied warranty to consumers, including Plaintiffs;
4 Ortho Evra™ was not of merchantable quality or safe and fit for its intended use.

5 89. Consumers, including Plaintiffs, and the medical community, reasonably relied
6 upon Defendants' implied warranty for Ortho Evra™.

7 90. Ortho Evra™ reached consumers without substantial change in the condition
8 in which it was manufactured and sold by Defendants.

9 91. As a direct and proximate result of Defendants' actions, Plaintiffs suffered
10 serious personal injuries. In addition, Plaintiffs required and will continue to require
11 healthcare and services. Plaintiffs incurred and will continue to incur medical and related
12 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the
13 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation
14 of preexisting conditions and activation of latent conditions, and other losses and damages.
15 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include
16 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
17 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.
18 Plaintiffs have suffered loss of wages and wage-earning capacity.

19 92. Defendants' conduct as described above was committed with knowing,
20 conscious, wanton, willful, and deliberate disregard for the value of human life and rights
21 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages
22 so as to punish Defendant and deter it from similar conduct in the future.

23 **WHEREFORE**, Plaintiffs demand judgment against Defendants and seek
24 compensatory damages, and exemplary and punitive damages together with interest, the costs
25 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

26 / / /

FIFTH CAUSE OF ACTION
(Fraudulent Misrepresentation)

93. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

94. Defendants made fraudulent misrepresentations with respect to Ortho Evra™ in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Ortho Evra™ had been tested and found to be safe and effective for the treatment and prevention of osteoporosis; and

b. Defendants represented that Ortho Evra™ was safer than other alternative medications.

95. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Ortho Evra™ to consumers, including Plaintiffs, and the medical community.

96. The representations were made by Defendants with the intent that doctors and patients, including Plaintiffs, rely upon them.

97. Defendants' representations were made with the intent of defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and encourage the sale of Ortho Evra™.

98. Plaintiffs' doctors, and others relied upon the representations.

99. Defendants' fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety and welfare of consumers, including Plaintiffs.

100. As a direct and proximate result of Defendants' actions, Plaintiffs suffered serious personal injuries. In addition, Plaintiffs required and will continue to require

1 healthcare and services. Plaintiffs incurred and will continue to incur medical and related
2 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the
3 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation
4 of preexisting conditions and activation of latent conditions, and other losses and damages.
5 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include
6 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
7 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.
8 Plaintiffs have suffered loss of wages and wage-earning capacity.

9 101. Defendants' conduct as described above was committed with knowing,
10 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
11 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages
12 so as to punish Defendant and deter it from similar conduct in the future.

13 WHEREFORE, Plaintiffs demand judgment against Defendants and seek
14 compensatory damages, and exemplary and punitive damages together with interest, the costs
15 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

16 **SIXTH CAUSE OF THE ACTION**
17 **(Fraudulent Concealment)**

18 102. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

19 103. Defendants made fraudulent misrepresentations with respect to Ortho Evra™
20 in the following particulars:

21 a. Defendants represented through its labeling, advertising, marketing
22 materials, detail persons, seminar presentations, publications, notice letters, and regulatory
23 submissions that Ortho Evra™ was safe and fraudulently withheld and concealed information
24 about the substantial risks of using Ortho Evra™; and

25 b. Defendants represented that Ortho Evra™ was safer than other
26 alternative medications and fraudulently concealed information which demonstrated that

1 Ortho Evra™ was not safer than alternatives available on the market.

2 104. Defendants had sole access to material facts concerning the dangers and
3 unreasonable risks of Ortho Evra™.

4 105. The concealment of information by Defendants about the risks of Ortho Evra™
5 was intentional, and the representations made by Defendants were known by Defendants to
6 be false.

7 106. The concealment of information and the misrepresentations about Ortho
8 Evra™ were made by Defendants with the intent that doctors and patients including
9 Plaintiffs, rely upon them.

10 107. Plaintiffs' doctors, and others relied upon the representations and were unaware
11 of the substantial dental and oral risks of Ortho Evra™ which Defendants concealed from
12 Plaintiffs' doctors and Plaintiffs.

13 108. As a direct and proximate result of Defendants' actions, Plaintiffs suffered
14 serious personal injuries. In addition, Plaintiffs required and will continue to require
15 healthcare and services. Plaintiffs incurred and will continue to incur medical and related
16 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the
17 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation
18 of preexisting conditions and activation of latent conditions, and other losses and damages.
19 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include
20 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.
21 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.
22 Plaintiffs have suffered loss of wages and wage-earning capacity.

23 109. Defendants' conduct as described above was committed with knowing,
24 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
25 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages
26 so as to punish Defendant and deter it from similar conduct in the future.

1 **WHEREFORE**, Plaintiffs demand judgment against Defendants and seek
 2 compensatory damages, and exemplary and punitive damages together with interest, the costs
 3 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

4 **SEVENTH CAUSE OF ACTION**
 (Equitable Relief)
 5 **(Medical Monitoring Program and Proper Labeling)**

6 110. Plaintiffs restate the allegations set forth above as it fully rewritten herein.

7 111. As a direct and proximate result of Defendants' acts, Plaintiffs face an
 8 increased susceptibility to injuries as described herein. The irreparable threat to their health
 9 can only be mitigated by the creation of a medical monitoring fund to provide for a medical
 10 monitoring program, including; notifying Plaintiffs and subclasses of the defects and the
 11 potential medical harm; funding of a program for the surgical treatment of thrombolytic
 12 events; funding a study for the long term effects of Ortho Evra™ upon Plaintiffs; gathering
 13 and forwarding to treating physicians information relating to the diagnosis and treatment of
 14 injuries which may result from the product; and funding for diagnosis and preventative
 15 medical treatment, particularly dental and oral monitoring.

16 112. Plaintiffs have no adequate remedy in law in that monetary damages alone do
 17 not compensate for the insidious and continuing nature of the harm to them, and only a
 18 medical monitoring program which notified Plaintiffs and aids in correcting the problems can
 19 prevent the greater harms which may not occur immediately and which may be preventable,
 20 if proper research is conducted and the health risk are diagnosed and treated before they
 21 occur or become worse.

22 113. Plaintiffs suffered irreparable harm as alleged herein and, in the absence of
 23 equitable relief, Plaintiffs will suffer further irreparable harm such as death and severe and
 24 debilitating injuries from continued retention of the defective drug. Without a medical
 25 monitoring program, Plaintiffs might not receive prompt medical care which could prolong
 26 their productive lives, increase prospects for improvement and minimize disability.

1 114. Additionally, Defendants have refused to fully abide by the FDA's request to
2 amend the Ortho Evra™ product labeling information to warn physicians and patients about
3 the risk of thrombolytic events. Because of their failure, prescribing physicians are unable
4 to warn patients to be aware of precursor symptoms which, if properly observed and reported
5 to the physician, could result in discontinuation of Ortho Evra™ therapy and the prevention
6 or mitigation of serious injury, including thrombolytic events. This Court should use its
7 equitable powers, in the interest of the public safety and in order to make sure that
8 prescribing physicians have a complete understanding of the risks associated with Ortho
9 Evra™ to require Defendant to change its label in a format approvable by the FDA to
10 adequately warn physicians and Ortho Evra™ patients about the risk of thrombolytic events,
11 and steps which can be taken to prevent or mitigate its occurrence.

12 WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable
13 relief in the form of a medical monitoring program this Court's order that Defendants change
14 the labeling of Ortho Evra™ to appropriately warn of the risk of thromboembolic and/or
15 thrombolytic events.

16 **EIGHTH CAUSE OF ACTION**
17 **(Violation of Business & Profession Code Section 17200)**

18 115. Plaintiffs restate the allegations set forth above as it fully rewritten herein.

19 116. Plaintiffs are informed and believe and allege that Defendants, by the acts and
20 misconduct alleged herein, violated Business and Professions Code sections 17200.

21 117. California Business & Professions Code Section 17200 provides that unfair
22 competition shall mean and include "all unlawful, unfair or fraudulent business practices and
23 unfair, deceptive, untrue or misleading advertising."

24 118. The acts and practices described herein were and are likely to mislead the
25 general public and therefore constitute unfair business practices within the meaning of
26 Business & Professions Code Section 17200. The acts and untrue and misleading advertising

1 set forth in presiding paragraphs are incorporated by reference and are, by definition,
2 violations of Business & Professions Code Section 17200. This conduct includes, but is not
3 limited to:

4 a. Representing to Plaintiffs, Plaintiffs's physicians and the general public
5 that Ortho Evra™ was safe, fit and effective for human consumption, knowing that said
6 representations were false, and concealing from the Plaintiffs, Plaintiffs' physicians and the
7 general public that Ortho Evra™ has a serious propensity to cause injuries to users;

8 b. Engaging in advertising programs designed to create the image,
9 impression and belief by consumers, physicians and others that the use of Ortho Evra™ was
10 safe for human use, had fewer side effects and adverse reactions than other methods for
11 osteoporosis, constituted a convenient, safe form for treating osteoporosis and would not
12 interfere with daily life, even though the Defendants knew these to be false, and even though
13 the Defendants had no reasonable grounds to believe them to be true;

14 c. Purposely downplaying and understating the health hazards and risks
15 associated with Ortho Evra™; and

16 d. Issuing promotional literature deceiving potential users of Ortho Evra™
17 by relaying positive information and manipulating statistics to suggest widespread
18 acceptability, while downplaying the known adverse and serious health effects and
19 concealing material relevant information regarding the safety of Ortho Evra™.

20 119. These practices constitute unlawful, unfair and fraudulent business acts or
21 practices, within the meaning of California Business & Professions Code Section 17200, as
22 well as unfair, deceptive, untrue and misleading advertising as prohibited by California
23 Business & Professions Code Section 17500, as set forth herein.

24 120. The unlawful, unfair and fraudulent business practices of Defendants described
25 above present a continuing threat to members of the public in that Defendants continue to
26 engage in the conduct described therein.

1 121. As a result of their conduct described above, Defendants have been unjustly
 2 enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of
 3 millions of dollars in ill-gotten gains from the sale and prescription of Ortho Evra™ in
 4 California, and other states, sold in large part as a result of the acts and omissions described
 5 herein.

6 122. Because of the fraudulent misrepresentations made by Defendants as detailed
 7 above, and the inherently unfair practice of committing a fraud against the Plaintiffs and
 8 public by intentionally misrepresenting and concealing material information, the acts of
 9 Defendant described herein constitute unfair or fraudulent business practices.

10 123. Plaintiffs, pursuant to California Business & Professions Code Section 17203,
 11 seek an order of this court compelling the Defendant to provide restitution, and to disgorge
 12 the monies collected and profits realized by Defendants, and each of them, as a result of their
 13 unfair business practices.

14 124. Defendants' acts were willful, wanton, reckless and fraudulent; hence,
 15 Plaintiffs are entitled to exemplary damages, inter alia.

16 **WHEREFORE**, Plaintiffs demand judgment against Defendants and seek
 17 compensatory damages, disgorgement, restitution, and exemplary and punitive damages
 18 together with interest, the costs of suit, attorneys' fees and such other and further relief as the
 19 Court deems just and proper.

20 **NINTH CAUSE OF ACTION**
 21 **(Violation of Business & Profession Code Section 17500)**

22 125. Plaintiffs restate the allegations set forth above as it fully rewritten herein.

23 126. Plaintiffs are informed and believe and thereon allege that Defendants, by the
 24 acts and misconduct alleged herein, violated Business & Professions Code Section 17500.

25 127. Plaintiffs hereby seek restitution, as well as and punitive damages against
 26 Defendants for their violations of section 17500.

1 128. California Business & Professions Code section 17500 provides that it is
2 unlawful for any person, firm, corporation or association to dispose of property or perform
3 services, or to induce the public to enter into any obligation relating thereto, through the use
4 of untrue or misleading statements.

5 129. At all times herein mentioned, Defendants have committed the acts of
6 disseminating untrue and misleading statements as defined by Business & Professions Code
7 Section 17500 by engaging in the following acts and practices with intent to induce members
8 of the public to purchase and use Ortho Evra™:

9 a. Representing to Plaintiffs, Plaintiffs's physicians and the general public
10 that Ortho Evra™ was safe, fit and effective for human consumption, knowing that said
11 representations were false, and concealing from the Plaintiffs, Plaintiffs' physicians and the
12 general public that Ortho Evra™ have a serious propensity to cause injuries to users;

13 b. Engaging in advertising programs designed to create the image,
14 impression and belief by consumers, physicians and others that the use of Ortho Evra™ was
15 safe for human use, had fewer side effects and adverse reactions than other methods for
16 treating osteoporosis, constituted a convenient, safe form for treating osteoporosis and would
17 not interfere with daily life, even though the Defendants knew these to be false, and even
18 though the Defendants had no reasonable grounds to believe them to be true;

19 c. Purposely downplaying and understating the health hazards and risks
20 associated with Ortho Evra™; and

21 d. Issuing promotional literature deceiving potential users of Ortho Evra™
22 by relaying positive information and manipulating statistics to suggest widespread
23 acceptability, while downplaying the known adverse and serious health effects and
24 concealing material relevant information regarding the safety of Ortho Evra™.

25 130. The foregoing practices constitute false and misleading advertising within the
26 meaning of California Business & Professions Code Section 17500.

1 with interest, the costs of suit, attorneys' fees and such other and further relief as the Court
2 deems just and proper.

3 **ELEVENTH CAUSE OF ACTION**
4 **(Punitive Damages)**

5 136. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

6 137. Defendants have repeatedly engaged in a pattern of conduct of deliberately
7 avoiding FDA recommendations as to public hazards which should be warned about.

8 138. Defendants' acts were willful and malicious in that Defendants' conduct was
9 carried on with a conscious disregard for the safety and rights of Plaintiffs and all others
10 taking Ortho Evra™. Defendants' unconscionable conduct thereby warrants an assessment
11 of exemplary and punitive damages in an amount appropriate to punish Defendants and deter
12 similar conduct in the future.

13 WHEREFORE, Plaintiffs demand judgment against Defendants and seek
14 compensatory damages, and exemplary and punitive damages together with interest, the costs
15 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

16 **PRAYER FOR RELIEF**

17 WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and/or
18 severally, as follows:

- 19 a. For general damages in an amount to be proven at the time of trial;
20 b. For special damages in an amount to be proven at time of trial;
21 c. For exemplary and punitive damages in an amount to be proven at the time of
22 trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the
23 injurious conduct alleged herein;
24 d. For prejudgment and post-judgment interest on the above general and special
25 damages;
26 e. For disgorgement of profits;

- 1 f. For restitution;
2 g. For costs and attorneys' fees; and
3 h. All other relief that Plaintiffs may be entitled to at equity or at law, including
4 but not limited to the funding of a medical monitoring program and compelling Defendants
5 to adequately warn about the risk of thrombolytic and other adverse events, associated with
6 use of Ortho Evra™.

7 **DEMAND FOR JURY TRIAL**

8 Plaintiffs demand a trial by jury on all claims so triable in this action.

9 Dated: February 9, 2007

Respectfully submitted,

10 PHILLIPS & ASSOCIATES

11
12 By 

13 Robert F. Clarke, Esq.
14 3030 North Third Street, Suite 1100
15 Phoenix, Arizona 85012
16 Attorneys for Plaintiffs
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CASE NUMBER: CGC-07-460481 MELONEY WRIGHT VS. ORTHO-MCNEIL CORPORATION

NOTICE TO PLAINTIFF

A Case Management Conference is set for

DATE: JUL-20-2007

TIME: 9:00AM

**PLACE: Department 212
400 McAllister Street
San Francisco, CA 94102-3680**

All parties must appear and comply with Local Rule 3.

CRC 3.725 requires the filing and service of a case management statement form CM-110 no later than 15 days before the case management conference.

However, it would facilitate the issuance of a case management order **without an appearance** at the case management conference if the case management statement is filed, served and lodged in Department 212 twenty-five (25) days before the case management

Plaintiff must serve a copy of this notice upon each party to this action with the summons and complaint. Proof of service subsequently filed with this court shall so state.

ALTERNATIVE DISPUTE RESOLUTION POLICY REQUIREMENTS

IT IS THE POLICY OF THE SUPERIOR COURT THAT EVERY CIVIL CASE PARTICIPATE IN EITHER MEDIATION, JUDICIAL OR NON-JUDICIAL ARBITRATION, THE EARLY SETTLEMENT PROGRAM OR SOME SUITABLE FORM OF ALTERNATIVE DISPUTE RESOLUTION PRIOR TO A MANDATORY SETTLEMENT CONFERENCE OR TRIAL.
(SEE LOCAL RULE 4)

Plaintiff must serve a copy of the Alternative Dispute Resolution Information Package on each defendant along with the complaint. All counsel must discuss ADR with clients and opposing counsel and provide clients with a copy of the Alternative Dispute Resolution Information Package prior to filing the Case Management Statement.

[DEFENDANTS: Attending the Case Management Conference does not take the place of filing a written response to the complaint. You must file a written response with the court within the time limit required by law. See Summons.]

Superior Court Alternative Dispute Resolution Coordinator
400 McAllister Street, Room 103
San Francisco, CA 94102
(415) 551-3876

See Local Rules 3.6, 6.0 C and 10 D re stipulation to commissioners acting as temporary judges